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TOPICAL HAZARD EVALUATION OF CANDIDATE INSECT REPELLENT AI3-365--ETC(U)
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USAEHA-51-0844-78

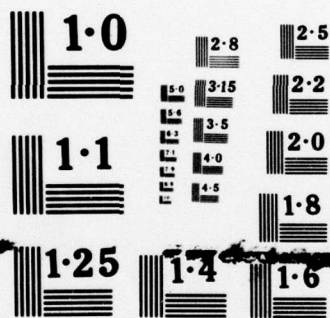
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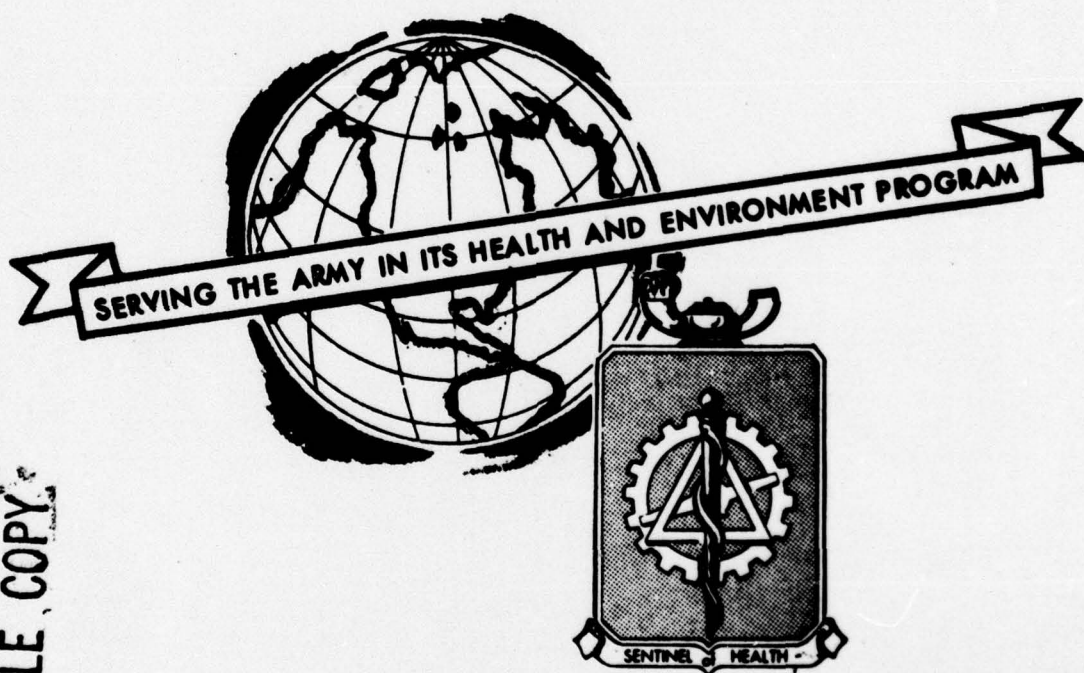
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TOPICAL HAZARD EVALUATION OF
CANDIDATE INSECT REPELLENT AI3-36541-aGa
USDA PROPRIETARY COMPOUND
STUDY NO. 51-0844-78
JANUARY 1976-OCTOBER 1977

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REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1. REPORT NUMBER 51-0844-78	2. GOVT ACCESSION NO.	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitle) Topical Hazard Evaluation of Candidate Insect Repellent AI3-36541-aGa, USDA Proprietary Compound Study No. 51-0844-78, January 1976 - October 1977		5. TYPE OF REPORT & PERIOD COVERED Final, Jan 76 - Oct 77
7. AUTHOR(s) MAURICE H. WEEKS BRENDA J. DeSENA		6. PERFORMING ORG. REPORT NUMBER 51-0844-78
8. PERFORMING ORGANIZATION NAME AND ADDRESS US Army Environmental Hygiene Agency Aberdeen Proving Ground, MD 21010		9. CONTRACT OR GRANT NUMBER(s)
11. CONTROLLING OFFICE NAME AND ADDRESS Commander US Army Health Services Command Fort Sam Houston, TX 78234		10. PROGRAM ELEMENT PROJECT, TASK AREA & WORK UNIT NUMBERS Final report
14. MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)		12. REPORT DATE Oct 77
16. DISTRIBUTION STATEMENT (of this Report) Approved for public release; distribution unlimited.		13. NUMBER OF PAGES 6
17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)		15. SECURITY CLASS. (of this report) Unclassified
18. SUPPLEMENTARY NOTES		15a. DECLASSIFICATION/DOWNGRADING SCHEDULE
19. KEY WORDS (Continue on reverse side if necessary and identify by block number) AI3-36541-aGa skin irritation USDA Proprietary Compound eye irritation Topical Hazard Evaluation Candidate Insect Repellent		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) A preliminary hazard evaluation of AI3-36541-aGa was performed by means of laboratory studies using rats, rabbits and guinea pigs. The technical grade compound caused only mild eye and skin irritation but did not produce photochemical irritation in rabbits, did not sensitize guinea pigs and did not demonstrate an acute ingestion hazard. It is recommended that AI3-36541-aGa be approved for further testing as a candidate insect repellent. It should, however, be used with caution around the eyes and mucosa. ✓		

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DEPARTMENT OF THE ARMY
U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY
ABERDEEN PROVING GROUND, MARYLAND 21010

Mr. Weeks/cf/584-3980

8 MAY 1978

HSE-LT/WP

SUBJECT: Topical Hazard Evaluation of Candidate Insect Repellent
AI3-36541-aGa, USDA Proprietary Compound, Study No. 51-0844-78,
January 1976-October 1977

Executive Secretary
Armed Forces Pest Control Board
Forest Glen Section, WRAMC
Washington, DC 20012

A summary of the pertinent findings and recommendations of the inclosed report follows:

A preliminary hazard evaluation of AI3-36541-aGa was performed by means of laboratory studies using rats, rabbits, and guinea pigs. The technical grade compound caused only mild eye and skin irritation but did not produce photochemical irritation in rabbits, did not sensitize guinea pigs and did not demonstrate an acute ingestion hazard. It is recommended that AI3-36541-aGa be approved for further testing as a candidate insect repellent. It should, however, be used with caution around the eyes and mucosa.

FOR THE COMMANDER:

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ABERDEEN PROVING GROUND, MARYLAND 21010

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TOPICAL HAZARD EVALUATION OF
CANDIDATE INSECT REPELLENT AI3-36541-aGa
USDA PROPRIETARY COMPOUND
STUDY NO. 51-0844-78
JANUARY 1976-OCTOBER 1977

1. AUTHORITY.

a. Letter, US Department of Agriculture - Agricultural Research Service, Southern Region, Insects Affecting Man Research Laboratory, Gainesville, Florida, 17 December 1975.

b. Memorandum of Understanding between the Department of the Army, Office of The Surgeon General; the US Army Health Services Command; the US Army Environmental Hygiene Agency; the Armed Forces Pest Control Board; and the US Department of Agriculture, effective 1970 with Amendment No. 1 effective August 1974.

2. REFERENCE. Toxicology Division Procedural Guide, USAEHA, 1972 revised 1976.

3. PURPOSE. The purpose of this program is to provide guidance for further entomological testing of the candidate insect repellent AI3-36541-aGa, USDA Proprietary Compound.

4. SUMMARY OF FINDINGS. A hazard evaluation of the candidate repellent AI3-36541-aGa was conducted by this Agency using New Zealand White rabbits for skin and eye studies, Hartley guinea pigs for a skin sensitization study and Sprague-Dawley rats for determination of oral toxicity. A tabular presentation of animal toxicity data developed in this Agency follows.*†

* In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals," US Department of Health, Education, and Welfare Publication No. (NIH) 74-23, revised 1972 - second printing 1974.

† The experiments reported herein were performed in animal facilities, fully accredited by the American Association of Accreditation of Laboratory Animal Care.

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Study No. 51-0844-78, Jan 76-Oct 77

Test	Results	Interpretation
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SKIN IRRITATION STUDIES

Rabbits

Single 24-hour application to intact and abraded skin of New Zealand White rabbits.

0.5 ml technical grade compound applied to each of six rabbits.

Compound AI3-36541-aGa caused a mild erythema and edema reaction to the intact skin and to the skin surrounding an abrasion of all rabbits.

USAEHA Category II (reference Appendix).

EYE IRRITATION STUDIES

Rabbits

Single 24-hour application of 0.1 ml technical grade compound to one eye of each of six New Zealand White rabbits.

Compound AI3-36541-aGa produced mild injury to the cornea in five of six rabbits, with some iritis and some irritation to the conjunctiva in all rabbits at 24 hours after application. Eyes appeared normal at 48 hours.

USAEHA Category C (reference Appendix).

APPROXIMATE LETHAL DOSE (ALD)

Oral

Rats (male) - no diluent technical grade material

ALD - 2900 mg/kg
- slight tremors at lethal dosages.

Presents little lethal hazard from acute accidental ingestion.

SENSITIZATION STUDIES

Guinea Pigs (Male)

Intradermal injections of 0.1 percent solution (w/v) of AI3-36541-aGa or of an 0.1 percent suspension of dinitrochlorobenzene (DNCB)* in a mixture containing 1 volume of propylene glycol and 29 volumes of saline.

* A known skin sensitizer.

Test	Results	Interpretation
Ten test guinea pigs received and challenged with an 0.1 percent solution of AI3-36541-aGa.	Challenge dose of test compound (last intradermal injection) produced no greater irritation reaction than that observed from the initial injection.	Compound AI3-36541-aGa did not sensitize guinea pigs and is not expected to cause a sensitization reaction in humans.
Ten positive control guinea pigs received and challenged with 0.1 percent suspension of DNCB.	Positive control (DNCB) produced a marked reaction in 10 out of 10 guinea pigs.	

PHOTOCHEMICAL SKIN IRRITATION STUDIES

Rabbits

A single application (0.05 ml) of a 25 percent (w/v) solution of AI3-36541-aGa in 95 percent ethyl alcohol, a 10 percent (w/v) oil of Bergamot solution (positive control) in 95 percent ethyl alcohol were applied to the intact skin of six rabbits. Five minutes after application, the rabbits were exposed to UV light (365 nm) for 30 minutes at a distance of 10-15 cm.

AI3-36541-aGa did not cause a photochemical irritation reaction under test conditions.

Positive control application and irradiation caused greater irritant reaction than in unirradiated areas.

Compound AI3-36541-aGa did not cause a photochemical irritation reaction under test conditions and is not expected to cause photochemical irritation reactions in humans.

Control

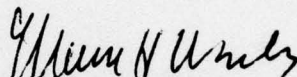
Following UV exposure, 0.05 ml of the test compound, and positive control were applied to additional skin area of the rabbits.

Ethanol solutions of test compound applied without subsequent irradiation caused no skin irritation reaction.

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5. CONCLUSIONS. The candidate insect repellent AI3-36541-aGa (USDA Proprietary) caused a mild skin and eye irritant reaction but presents no acute hazard from photochemical or sensitization contact or from acute ingestion.

6. RECOMMENDATIONS. Under the provisions of the Memorandum of Understanding (paragraph 1b), it is recommended that AI3-36541-aGa (USDA Proprietary Compound) be approved for further testing as a candidate insect repellent. Eye irritation may result from accidental contact. It should be used with caution around the eyes and muscosa and washed out immediately if it should contact those areas.

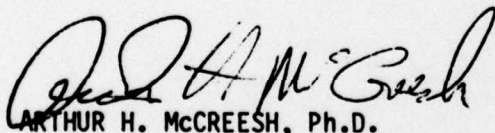


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APPENDIX

TOPICAL HAZARD EVALUATION PROGRAM
DEFINITIONS OF CATEGORIES OF COMPOUNDS BEING
CONSIDERED FOR ACUTE SKIN APPLICATION

CATEGORY I - Compounds producing no primary irritation of the intact skin or no greater than mild primary irritation of the skin surrounding an abrasion. (INTERPRETATION: No restriction for acute application to the human skin.)

CATEGORY II - Compounds producing mild primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should be used only on human skin found by examination to have no abrasions or may be used as a clothing impregnant.)

CATEGORY III - Compounds producing moderate primary irritation of the intact skin and the skin surrounding an abrasion. (INTERPRETATION: Should not be used directly on the skin without a prophetic patch test having been conducted on humans to determine irritation potential to human skin. May be used without patch testing, with extreme caution, as clothing impregnants. Compound should be resubmitted in the form and at the intended use concentration so that its irritation potential can be reexamined using other test techniques on animals.)

CATEGORY IV - Compounds producing moderate to severe primary irritation of the intact skin and of the skin surrounding an abrasion and, in addition, producing necrosis, vesiculation and/or eschars. (INTERPRETATION: Should be resubmitted for testing in the form and at the intended use concentration. Upon resubmission, its irritation potential will be reexamined using other test techniques on animals. prior to possible prophetic patch testing in humans, at concentrations which have been shown not to produce primary irritation in animals.)

CATEGORY V - Compounds impossible to classify because of staining of the skin or other masking effects owing to physical properties of the compound. (INTERPRETATION: Not suitable for use on humans.)

EYE CATEGORIES:

A. Compounds noninjurious to the eye. INTERPRETATION: Irritation of human eyes is not expected if the compound should accidentally get into the eyes, provided it is washed out as soon as possible.

B. Compounds producing mild injury to the cornea. INTERPRETATION: Should be used with caution around the eyes.

C. Compounds producing mild injury to the cornea, and in addition some injury to the conjunctiva. INTERPRETATION: Should be used with caution around the eyes and mucosa.

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D. Compounds producing moderate injury to the cornea. INTERPRETATION: Should be used with extreme caution around the eyes.

E. Compounds producing moderate injury to the cornea, and in addition producing some injury to the conjunctiva. INTERPRETATION: Should be used with extreme caution around the eyes and mucosa.

F. Compounds producing severe injury to the cornea and to the conjunctiva. INTERPRETATION: Should be used with extreme caution. It is recommended that use be restricted to areas other than the face.